



Fresenius Medical Care

FEB - 3 2011

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content in this 510(k) summary has been provided in conformance with 21 CFR Part 807.92

A. Submitter's Information:

Name: Fresenius Medical Care North America

Address: 920 Winter Street
Waltham, MA 02451-1457

Phone: 781-699-9505

Fax: 781-699-9635

Contact Person: Randy Quinn, Lead Regulatory Affairs Specialist - Devices

Date of Preparation: December 1, 2010

B. Device Name:

Trade Name: 2008K@home with Wireless Wetness Detector

Common Name: Hemodialysis Machine

Product Code/Classification Panel: 78 KDI / Gastroenterology/Urology

Classification Name: High Permeability Hemodialysis System, Class II per § 876.5860

C. Legally Marketed Predicate Device (unmodified devices):

The Fresenius 2008K@home with Wireless Wetness Detector is a modified version of the Fresenius 2008K, which was cleared under the following premarket notification:

Fresenius 2008K Dialysate Delivery System

- K994267 (3/10/2000)

D. Device Description:

The Fresenius 2008K@home machine is a modified version of the 2008K 3-stream hemodialysis machine. Modifications to the device interface are designed to improve and simplify the training and process of performing hemodialysis. This modified user interface is intended to make it easier for patients and/or their caregivers to deliver hemodialysis safely and effectively in the home environment.

Additionally, the wireless wetness detector (WetAlert), an optional accessory to the 2008K@home, is a disposable device that detects leaks. During treatment, the WetAlert device transmits radio signals to the corresponding 2008K@home hemodialysis machine and alerts the machine if it detects a blood or water leak. During a wetness alarm, the 2008K@home hemodialysis machine will automatically stop the blood pump, close the venous clamp, and sound an alarm.

E. Indications for Use:

2008K@home Indications for Use:

The Fresenius 2008K@home is indicated for acute and chronic dialysis therapy in an acute or chronic facility. The 2008K@home is also indicated for hemodialysis in the home and must be observed by a trained and qualified person as prescribed by a physician.

Wireless Wetness Detector Indications for Use:

The Wireless Wetness Detector is indicated for use with the Fresenius 2008K@home hemodialysis machine and is an optional accessory to aid in the detection of blood and water leaks during hemodialysis. Home hemodialysis using the detector must be observed by a trained and qualified person as prescribed by a physician.

F. Technological Characteristics

The Fresenius 2008K@home is a modified version of the Fresenius 2008K Dialysate Delivery System. Modifications were made to the user interface and the Wireless Wetness Detector was added as an optional accessory to facilitate the device's use by home patients. The performance data described below demonstrate that the modified Fresenius 2008K@home with Wireless Wetness Detector is substantially equivalent to the Fresenius 2008K (K994267) Dialysate Delivery System.

G. Performance Data

1. Summary of non-clinical data submitted with the premarket notification of the device

Full system validation and software regression testing was performed to ensure that the modifications to the 2008K@home with Wireless Wetness Detector function as intended and that the modifications did not negatively impact the overall 2008K@home hemodialysis machine system. Testing included:

- Software validation and regression testing
- Electromagnetic compatibility (EMC) testing
- Electrical safety testing

The results from the testing demonstrated that all modifications functioned as intended and met pre-determined acceptance criteria.

2. Summary of clinical data obtained

FMCNA conducted clinical studies demonstrating that the 2008K@home can be used as safely and effectively at home as in the dialysis clinic. The company collected and evaluated safety data from over 500 in-center and 500 home hemodialysis treatments. Additionally, FMCNA conducted an evaluation of treatment adequacy and safety from 29 subjects who transitioned from in-center to home hemodialysis.

Usability testing also was conducted in the clinic and home settings to confirm the safe and effective use of the modified device.

H. Conclusion

The non-clinical and clinical data demonstrate that the 2008K@home is as safe and effective, and performs as well, as the cleared 2008K.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WQ66-G609
Silver Spring, MD 20993-0002

FEB 3 2011

Mr. Randolph Quinn
Lead Regulatory Affairs Specialist
Fresenius Medical Care North America
920 Winter Street
WALTHAM MA 02451-1457

Re: K070049
Trade/Device Name: Fresenius 2008K@Home with Wireless Wetness Detector
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: ONW and ODX
Dated: December 10, 2010
Received: December 13, 2010

Dear Mr. Quinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

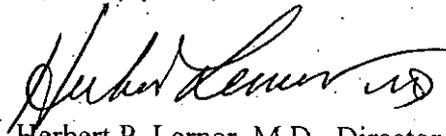
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

Indications for Use

510(k) Number (if known): K070049

Device Name:

Fresenius 2008K@home

Indications for Use:

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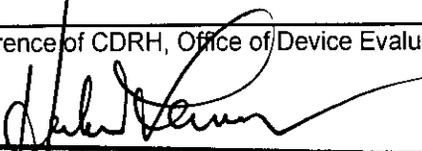
Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and
Urological Devices

510(k) Number K070049